

In re Application of:
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Application No.: 09/708,693
Filed: November 7, 2000
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PATENT
Atty Docket No.: JHU1120-15

REMARKS

Claims 1, 11, 19, 22, 26, 29, 32-33, 37 and 40 have been amended. Claims 2-4, 20-21, 30, 34-36 and 38 have been canceled without prejudice or disclaimer. Claims 42 and 43 have been added. Claims 5-8, 12-14, 16-18 and 23-25 were previously canceled. Subsequent to the entry of the present amendment, claims 1, 9-11, 15, 19, 22 and 26-29, 31-33, 37, 39-43 are pending and at issue. The amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

Applicants acknowledge and thank the Office for the following: entering the amendment filed September 25, 2002; withdrawing the finality of the Office Action mailed May 7, 2002; and withdrawing the species election of murine sequences SEQ ID NOs: 3 and 4 as filed in the amendment in response to the Restriction Requirement mailed July 16, 2001. Thus, claims 1-4, 9-11, 15, 19-22 and 26-41 are pending and at issue.

I. Amendment to the Claims

Claims 1, 19, 22, 26, 33 and 37 have been amended to incorporate the subject matter of claims 2-4, 20-21, 30, 34-36 and 38 have been subsequently canceled.

Also, claims 42 and 43 have been added. These claims are supported in claims 22 and 36, which have been canceled.

Claims 11, 29, 32 and 40 have been amended to recite an "isolated host cell".

All amendments to the claims are fully supported by the specification and original claims and no new matter has been added.

II. Objections to the Claims

According to the Office Action, claim 4 and 5 are objected to for allegedly claiming substantially duplicate or identical subject matter to claims 30 and 36, and 31, respectively. Applicants respectfully traverse this objection as follows.

Although claims 30, 36 and 31 have been canceled and the objection with regards to these claims is moot, Applicants submit that claims 30, 36 and 31 were not duplicate claims or slight variations thereof. Claim 4 depends on independent claim 1 which is directed to polynucleotides encoding for peptides corresponding to amino acid residues about 1 to 20. Claim 30 depends on independent claim 19 which is directed to polynucleotides encoding for peptides corresponding to amino acid residues from about 268 to 374. Claim 36 depends on independent claim 33, which is directed to polynucleotides encoding for peptides corresponding to amino acid residues from about 20 to 262. Thus, claims 3, 30 and 36 all claim different inventive aspects.

Similarly, claim 15 is not duplicative of claim 31. Claim 15 depends on independent claim 1, which is directed to polynucleotides encoding peptides corresponding to amino acid residues about 1 to 20 of a full length promyostatin polypeptide. Claim 31 depends on independent claim 19, and is directed to polynucleotides encoding peptides corresponding to amino acid residues from about 268 to 374 of a full length promyostatin polypeptide. Also, neither claims 15 nor 31 are duplicative of claims 4 and 30, respectively, because 15 and 31 are directed to polynucleotide sequences, whereas claims 4 and 30 are directed to polypeptide sequences.

Thus, based on the foregoing, there are no duplicative claims as each claim depends from and is directed to different inventive aspects of the claimed invention.

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III. Double patenting

Claims 1-4, 9-11, 15, 19-22 and 27-40 are rejected under nonstatutory obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent 5,827,733.

A Terminal Disclaimer, disclaiming any patent term of the subject application that may extend beyond the term of U.S. Patent No. 5,827,733, U.S. Patent No. 6,500,664 and U.S. Patent No. 6,465,239 is submitted herewith. Accordingly, it is respectfully requested that the double patenting rejection be withdrawn.

Also, Applicants acknowledge that the double patenting rejection of claims 21-23 in the Office Action mailed May 7, 2002 has been withdrawn due cancellation of the claims.

IV. Rejections under 35 U.S.C. §112, First Paragraph (written description)

Claims 1-3, 9-11, 19-21, 27-29, 32-35 and 38-40 stand rejected under on 35 U.S.C. §112, first paragraph for allegedly not containing a sufficient written description of the invention. This rejection is maintained for reasons of record as stated in the Final Office Action mailed May 7, 2002, and as applied to new claims 32-35 and 38-40. Applicants respectfully traverse the rejection as it applies to the amended claims.

According to the present Office Action, which relies on the Office Action mailed May 7, 2002 and the Advisory Action mailed November 4, 2002, Applicants describe three aspects of promyostatin polypeptides and their respective functions: a signal peptide (corresponding to amino acids about 1 to 20 of a full length promyostatin polypeptide), which interacts with the mature or parent protein; a promyostatin prodomain (corresponding to amino acids about 20 to 262 or 263 of a full length promyostatin polypeptide) which inhibits myostatin binding to the activin receptor; and a C-terminal polypeptide (corresponding to amino acids about 267 or 268 to 374 or 375 of a full length promyostatin polypeptide), which binds to the activin receptor (summarized; see page 3 of the Office Action mailed May 7, 2002). Yet, according to the Office Actions, the claims allegedly encompass peptides that affect all steps in myostatin signaling in

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all way, and that no other promyostatin “portions” are allegedly described (page 3 of the Office Action mailed December 7, 2005)”.

Applicants submit that the claims have been amended to incorporate the subject matter of dependent claims 2-4, 20-21, 30, 34-36 and 38, which have been subsequently canceled. Although the claims have been amended to improve their form, they encompass substantially the same subject matter and clearly define particular domains of promyostatin by both structure and function. Thus, the claimed invention is sufficiently described in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Accordingly, withdrawal of rejection of claims 1-3, 9-11, 19-21, 27-29, 32-35 and 38-40 under 35 U.S.C. § 112, first paragraph is respectfully requested.

V. Rejections under 35 U.S.C. §112, First Paragraph (enablement)

Claims 1-3, 9-11, 19-21, 27-29, 32-35 and 38-40 stand rejected under on 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one of skill in the art to make or use the invention. This rejection is maintained for reasons of record as stated in the Final Office Acton mailed May 7, 2002, and as applied to new claims 32-35 and 38-40. Applicants respectfully traverse the rejection as it applies to the amended claims.

According to the present Office Action, which relies on the Office Action mailed May 15, 2002, Applicants describe promyostatin functions including “all means of activation, inhibition, and affects on activation and inhibition... [and] that one skilled in the art would have to make any and all possible portions of myostatin and assay these for any and all possible effects on signaling and effects associated with signaling (see page 5 of the Office Action mailed

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May 15, 2002)". Thus, according to the Office Action, the claims are broadly drawn and would require undue experimentation for one of skill in the art.

Applicants submit that the claims have been amended to incorporate the subject matter of dependent claims 2-3, 35-36, 38-39 and 41-42, which have been subsequently canceled. That is, the above claims have been amended to include the particular "peptide portions" although encompassing substantially the same subject matter as they did prior to the amendment. The claims as amended clearly define particular domains of promyostatin by both structure and function. Thus, one skilled in the art would not be required to perform undue experimentation in order to make and use the claimed invention.

Also, according to the Office Action, claims 11, 32 and 40 are directed to a "host cell" or "cell" and allegedly embrace transgenic animals and plants which are not enabled by the specification. Claims 11, 29, 32 and 40 have been amended to recite an "isolated host cell" which is supported throughout the specification and original claims. That is, the specification describes various cell lines transfected with the polynucleotides of the claimed invention, e.g., at least COS and CHO cells.

Accordingly, withdrawal of rejection of claims 1, 34-35, 38 and 40-41 under 35 U.S.C. § 112, first paragraph is respectfully requested.

V. Rejections under 35 U.S.C. §112, Second paragraph (indefiniteness)

The Office Action remains silent as to the rejection of claims 1-4, 9-22 and 27-29 for allegedly being indefinite as stated in the Office Action mailed May 7, 2002 and the Advisory Action mailed November 4, 2002.

Applicants submit that since the above claims were amended in the amendment filed September 25, 2002 deleting or removing the allegedly indefinite phrases such as "peptide

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portion", "proteolytic fragment", and "functional peptide portion", this rejection is moot with regards to these claims, and the rejection is presumptively withdrawn.

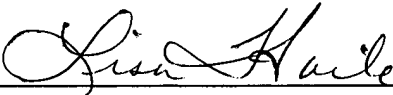
Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

A check in the amount of \$225.00 is enclosed as payment for the Two-Month Extension of Time Fee. No other fee is deemed necessary with the filing of this paper. However if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

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